

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appl. No.: 10/567,899
Applicant(s): Filho *et al.*
Filed: August 10, 2006
Art Unit: 1655
Examiner: Mi, Qiuwen

Confirmation No.: 7174

Title: PHARMACEUTICAL COMPOSITION COMPRISING PLANT MATERIAL OR TRICHILIA sp. ALONE OR IN ASSOCIATION WITH OTHER PLANT EXTRACTS FOR THE REVERSION/COMBAT AND/OR PREVENTION OF VENTRICULAR FIBRILLATION

Docket No.: 033794/307767
Customer No.: 00826

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

**RULE 37 C.F.R. §1.132 DECLARATION
of DR. IRINEU TADEU VELASCO**

I, Dr. Irineu Tadeu Velasco, do hereby declare and say as follows:

1. I am skilled in the art of the field of the invention. I received a Ph.D. in Physiology and Pharmacology at Biomedical Sciences Institute of USP and obtained medical degree from Medical Sciences School of Santa Casa of São Paulo - FCMSCSP. I am currently a Professor of Clinical Medicine at the Medical School of the University of São Paulo (USP).
2. I have read and understood the Office Action in the above case dated March 29, 2007.
3. The Examiner alleges in the Office Action of March 29, 2007 that ventricular fibrillation cannot be prevented. Items 4, 5, and 6 below present data supporting the methods set forth in the present claims relating to prevention of ventricular fibrillation with the prolonged use of *Trichilia catigua*.

4. To verify the use of *Trichilia catigua* in the prevention of ventricular fibrillation, when there are no antecedents of ventricular fibrillation, *in vitro* chronic experiments were carried out using 28 White New Zealand rabbits, weighing from 2 to 3 kg. The animals were divided into two groups: 1) Control group (9 animals) without treatment; and 2) Treated group (19 animals) treated with 100 mg/kg of orally administered *Trichilia catigua*, twice a day, during 15 days.

5. The animals were killed by a blow to the skull, the heart was then taken and rapidly suspended in a traditional Langendorff preparation, with retrograde coronary perfusion in a modified Krebs solution. They were then electrically stimulated according to the protocol previously described and observed. In the animals in which sustained ventricular fibrillation could not be induced, the stimulation protocol was repeated to confirm the result.

6. The results obtained are summarized in the table below. In the control group, of the 9 rabbits tested, 9 exhibited sustained ventricular fibrillation, no animal presented unsustained ventricular fibrillation and no animal suffered non-induced ventricular fibrillation. In the group treated for 15 days with 100mg/kg of *Trichilia catigua*, no animal presented sustained ventricular fibrillation, 14 animals presented unsustained ventricular fibrillation and, in 5 animals, no ventricular fibrillation was induced.

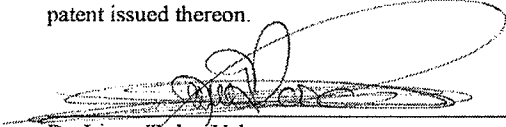
VF	SUSTAINED VF	UNSUSTAINED VF	None
Control group	9	0	0
Treated group	0	14	5

7. This experiment described above verifies that the use of an extract from plant material of the species *Trichilia catigua* A. Juss protects the hearts of rabbits from the occurrence of ventricular fibrillation (*i.e.*, ventricular fibrillation can be prevented).

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that

In re: Filho *et al.*
Appl. No.: 10/567,899
Filed: August 10, 2006
Page 3

these statements were made with the knowledge that willful false statements and the like are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.



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09/04/2007
Date